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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,131	05/06/2004	Matthew Iammatteo	Lifeline Medical	7250

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/840,131	IAMMATTEO, MATTHEW	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *9-16 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the invention of Group I, claims 1-8 and 17-20 in the reply filed on August 9, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-16 and 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 9, 2004.

Claim Rejections - 35 USC § 102

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 6, 17-18, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Bell et al. (US2003/0139381).

Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69, and 73 for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-5, 7-8, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al.

Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69, and 73 for example). Bell also teaches the pharmaceutical composition may be formulated into transdermal patch and vaginal ring (See paragraph [0039]).

Bell et al. does not expressly teach the product as formulated into transdermal patch and intra-vaginal ring.

It would have been obvious to one of ordinary skill in the art at the time of invention to formulate the composition of Bell into transdermal patch and vaginal ring.

One of ordinary skill in the art would have been motivated to formulate the composition of Bell into transdermal patch and vaginal ring. Since the composition of Bell can be formulated into transdermal patch and vaginal ring, it would be obvious to one of ordinary skill in the art to formulate the composition into either pharmaceutical

dosage forms as the selection of one or another known pharmaceutical dosage form would be seen as a simple selection from among obvious alternatives.

Claims 1-4, 6-7, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studd et al., (Advances in Gynecological Endocrinology, 12/2000, pages 83-89) and Freeman et al., (Archives of General Psychiatry, 1999;56(10):932-939).

Studd et al. teaches a method of employing estrogen patch and progesterone to treat Premenstrual syndrome (See pages 84-85).

Freeman et al. teaches selective serotonin reuptake inhibitors as useful in treating premenstrual syndrome (See the abstract).

The primary references do not expressly teach a composition comprising estrogen, progesterone, and selective serotonin reuptake inhibitors.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate estrogen, progesterone, and selective serotonin reuptake inhibitors into a single composition.

One of ordinary skill in the art would have been motivated to incorporate estrogen, progesterone, and selective serotonin reuptake inhibitors into a single composition. Combining two or more agents which are known to be useful to treat premenstrual syndrome individually into a single composition useful for the very same purpose is prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, formulating the combination composition into a transdermal patch or oral formulation

would be obvious as the selection of one or another known pharmaceutical dosage form would be seen as a simple selection from among obvious alternatives.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studd et al. and Freeman et al. as applied to claims 1-3, 6, 17-18, and 20 above, and further in view of Bell et al.

Studd and Freeman suggest a composition comprising estrogen, progesterone, and selective serotonin reuptake inhibitors.

Studd and Freeman do not expressly teach the product as formulated into transdermal patch and intra-vaginal ring.

Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69, and 73 for example). Bell also teaches the pharmaceutical composition may be formulated into transdermal patch and vaginal ring (See paragraph [0039]).

It would have been obvious to one of ordinary skill in the art at the time of invention to formulate estrogen-progesterone-selective serotonin reuptake inhibitors composition into vaginal ring.

One of ordinary skill in the art would have been motivated to formulate estrogen-progesterone-selective serotonin reuptake inhibitors composition into vaginal ring. Since vaginal ring is known to be useful in delivering estrogen-progesterone-selective serotonin reuptake inhibitors composition according to Bell et al., one of ordinary skill in the art would have been reasonably expected to be effective in formulating estrogen,

progesterone, and selective serotonin reuptake inhibitors into vaginal ring. The selection of one or another known pharmaceutical dosage form would be seen as a simple selection from among obvious alternatives

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617